Complete Summary

GUIDELINE TITLE

Surgical management of depressed cranial fractures.

BIBLIOGRAPHIC SOURCE(S)

Bullock MR, Chesnut R, Ghajar J, Gordon D, Hartl R, Newell DW, Servadei F, Walters BC, Wilberger J, Surgical Management of Traumatic Brain Injury Author Group. Surgical management of depressed cranial fractures. Neurosurgery 2006 Mar; 58(3 Suppl): S2-56-S2-60. [17 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISCLAIMER

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Closed (simple) depressed cranial fractures
- Open (compound) depressed cranial fractures

GUIDELINE CATEGORY

Evaluation Management Treatment

CLINICAL SPECIALTY

Emergency Medicine Neurological Surgery Neurology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To present recommendations for the surgical management of depressed cranial fractures

TARGET POPULATION

Patients with depressed cranial fractures

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Computed tomography scan
- 2. Glasgow Coma Scale score
- 3. Operative management
 - Surgical elevation
 - Debridement
 - Primary bone fragment replacement
- 4. Non-operative management
- 5. Antibiotic therapy

MAJOR OUTCOMES CONSIDERED

- Incidence of neurological deficits
- Incidence of infections
- Incidence of early and late epilepsy
- Mortality rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A MEDLINE computer search using the following key words: "skull" and "fracture" and "depressed" between 1975 and 2001 was performed. A total of 224 documents were found. The search was narrowed to include the key words: "surgery" or "operation" or "elevation". A total of 122 articles were found, 5 of which met the criteria for critical analysis. In addition, the reference lists of all

articles were reviewed, and additional articles were selected for background information

Papers primarily addressing the following topics were not included: patients with associated medical illnesses, sinus fractures, cranial base fractures, isolated orbital or facial fractures, and pre-computed tomography (CT) era reports. In general, papers with the following characteristics were also excluded: case series with less than 10 patients evaluated by CT scan and with incomplete outcome data (mortality or Glasgow outcome score), case reports, operative series with operations occurring longer than 14 days from injury. Several articles with case series of less than 10 patients were examined and reviewed because of the limited number of patient series evaluating the acute surgical management of depressed cranial fractures in the CT era.

NUMBER OF SOURCE DOCUMENTS

5

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classification of Evidence

When assessing the value of therapies or interventions, the available data was classified into one of the following three categories according to the following criteria:

Class I: Evidence from one or more well-designed, randomized, controlled clinical trials, including overviews of such trials

Class II: Evidence from one or more well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies

Class III: Evidence from case series, comparative studies with historical controls, case reports, and expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Evaluation and Weighting of the Evidence

The journal articles found have been carefully read and evaluated, including an assessment of the methodology used in the studies. This not only includes the establishment of the clinical question addressed (e.g., therapeutic effectiveness, diagnostic tests, prognostic studies, etc.) and type of study (randomized controlled trial, case-control study, case series, etc.), but also the quality of the study with respect to potential errors in design, execution, or conclusions reached. Therefore, studies that might, on the surface, represent evidence supporting one level of recommendation, may instead be flawed enough to be devalued to support a recommendation of lesser strength. The quality of the literature was evaluated in this way according to well-established criteria. All articles were cross-reviewed and disagreements were resolved by consensus.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Link Between Evidence and Guidelines

The general concept of relating strength of recommendations to strength of evidence reflecting varying degrees of clinical certainty was formalized into a scheme that has been followed by medical societies, including organized neurosurgery, from the inception of the Guideline development process. Despite problems with the strict application of this paradigm (some of which are displayed and discussed in this supplement), the scheme has the benefit of using scientific evidence rather than expert opinion for the substrate of the recommendations, although expert opinion is used to formulate the recommendations themselves, as well as to make judgments regarding the quality of the evidence. The evidence-based scheme used in these and all Guidelines regarding therapeutic effectiveness endorsed by the American Association of Neurological Surgeons and the Congress of Neurological Surgeons begins with classification of the literature into three categories of evidence (see "Rating Scheme for the Strength of the Evidence" above).

The classification of evidence into these three categories leads to the formulation of recommendations called Standards, Guidelines, and Options. Class I evidence is used to support treatment recommendations of the strongest type, practice Standards, reflecting a high degree of clinical certainty. Class II evidence is used to support Guidelines, reflecting a moderate degree of clinical certainty. Class III evidence supports practice Options reflecting unclear clinical certainty. This terminology was developed to indicate, in normal vocabulary, the strength of the recommendations on the basis of strong to weak medical evidence. In neurosurgery, this scheme has been used to formulate Guidelines, rather than a scheme that uses letters or numbers that have no grounding in language and are, therefore, more easily misinterpreted. The link between scientific evidence and recommendations has been highlighted in these Guidelines by presenting those studies in the scientific foundation that support the stated recommendation in boldface type.

Expert Judgment and Empirical Evidence

There are two ways in which expert judgment comes into Guideline development. The most common use of expert opinion is in developing recommendations for practice. This has been a usual method in the past (as well as the present, in the form of textbook chapters), but has more recently given way to more formalized approaches embraced by evidence-based medicine methodology, such as that used in this supplement. However, even in evidence-based methodology, expert opinion is used to evaluate the literature as well as to frame the concepts and wording of the recommendations. In addition, if the evidence is weak and conflicting, expert opinion is used to derive recommendations. This use is unavoidable, but the expert opinion is guided by the evidence published in the literature, rather than from personal experience alone.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Levels of Recommendations

Standards: Represent accepted principles of patient management that reflect a high degree of clinical certainty.

Guidelines: Represent a particular strategy or range of management strategies that reflect a moderate degree of clinical certainty.

Options: Are the remaining strategies for patient management for which there is unclear clinical certainty.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

In all Guidelines published under the auspices of the Brain Trauma Foundation and the American Association of Neurological Surgeons, other professional organizations were involved in either developing the Guidelines or reviewed and approved them. In these Surgical Management of Traumatic Brain Injury Guidelines, however, only neurosurgeons were involved. These neurosurgeons represent a wide range of organizations. There were representatives from the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, the European Brain Injury Consortium, the American College of Surgeons (Committee of Trauma) and the World Federation of Neurological Surgeons (Neurotrauma section) involved in the development of these Surgical Management of Traumatic Brain Injury Guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

"Degrees of Certainty" [Standards, Guidelines, Options] and "Classification of Evidence" [Class I to III] are defined at the end of the "Major Recommendations" field.

Note: All of the following recommendations are at the Options level, supported only by Class III scientific evidence.

Recommendations

Indications

- Patients with open (compound) cranial fractures depressed greater than the thickness of the cranium should undergo operative intervention to prevent infection.
- Patients with open (compound) depressed cranial fractures may be treated nonoperatively if there is no clinical or radiographic evidence of dural penetration, significant intracranial hematoma, depression greater than 1 cm, frontal sinus involvement, gross cosmetic deformity, wound infection, pneumocephalus, or gross wound contamination.
- Nonoperative management of closed (simple) depressed cranial fractures is a treatment option.

Timing

Early operation is recommended to reduce the incidence of infection.

Methods

- Elevation and debridement is recommended as the surgical method of choice.
- Primary bone fragment replacement is a surgical option in the absence of wound infection at the time of surgery
- All management strategies for open (compound) depressed fractures should include antibiotics.

Summary

The majority of studies are case series. No controlled, prospective clinical trials of treatment using surgical versus nonsurgical management have been published. The majority of data support debridement and elevation of grossly contaminated compound depressed cranial fractures as soon as possible after injury. However, several retrospective studies demonstrate successful nonoperative management of some patients with less-severe compound depressed cranial fractures on the basis of computed tomographic (CT) and clinical criteria. In the absence of gross wound infection at the time of presentation, immediate replacement of bone fragments seems not to increase the incidence of infection if surgery is performed expeditiously, and this replacement eliminates the need for subsequent

cranioplasty and its attendant risks and complications. No controlled data exist to support the timing of surgery or the use of one technique over another.

Definitions:

Degrees of Certainty

Standards: Represent accepted principles of patient management that reflect a high degree of clinical certainty.

Guidelines: Represent a particular strategy or range of management strategies that reflect a moderate degree of clinical certainty.

Options: Are the remaining strategies for patient management for which there is unclear clinical certainty.

Classification of Evidence on Therapeutic Effectiveness

Class I: Evidence from one or more well-designed, randomized, controlled clinical trials, including overviews of such trials

Class II: Evidence from one or more well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies

Class III: Evidence from case series, comparative studies with historical controls, case reports, and expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are all at the Option level, supported only by Class III scientific evidence (e.g., evidence from case series, comparative studies with historical controls, case reports, and expert opinion)

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate surgical management of depressed cranial fractures to improve clinical outcomes and reduce morbidity and mortality

POTENTIAL HARMS

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

As in all other areas of evidence-based medicine, these Guidelines have been formulated strictly in accordance with externally imposed constraints. Only clinical human-based literature has been reviewed. Only literature from 1975 through 2001 has been reviewed. Mainly literature in English, with far fewer articles in other languages, was reviewed. For these reasons, the reader must clearly understand that the scope and level of magnitude of the recommendations made here are distilled from the available literature and interpreted according to the rules of evidence-based medicine.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Bullock MR, Chesnut R, Ghajar J, Gordon D, Hartl R, Newell DW, Servadei F, Walters BC, Wilberger J, Surgical Management of Traumatic Brain Injury Author Group. Surgical management of depressed cranial fractures. Neurosurgery 2006 Mar; 58(3 Suppl): S2-56-S2-60. [17 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Mar

GUI DELI NE DEVELOPER(S)

Brain Trauma Foundation - Disease Specific Society

SOURCE(S) OF FUNDING

Brain Trauma Foundation Integra NeuroSciences

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

Congress of Neurological Surgeons - Professional Association

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format from the <u>Brain Trauma</u> Foundation Web site.

Print copies: Available from Jamshid Ghajar, MD, PhD, Brain Trauma Foundation, 708 Third Avenue, Suite 1810, New York, NY 10017, Email: ghajar@braintrauma.org

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction. Neurosurgery 2006 Mar; 58(3 Suppl): S2-1-S2-3.
- Methodology. Neurosurgery 2006 Mar; 58(3 Suppl): S2-4-S2-6.

Electronic copies: Available in Portable Document Format (PDF) from the <u>Brain Trauma Foundation Web site</u>.

Print copies: Available from Jamshid Ghajar, MD, PhD, Brain Trauma Foundation, 708 Third Avenue, Suite 1810, New York, NY 10017, Email: qhajar@braintrauma.org

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on August 15, 2006. The information was verified by the guideline developer on August 18, 2006.

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